

Remarks

This response is to the Non-Final Office Action dated January 14, 2009.

Claims 22, 25-27, 29, 35-38, 41-42, 46-68 and 78-80 are currently pending in this application. Claim 38 is amended. Support for this amendment can be found throughout the specification, for example at paragraphs 1, 9, 33, 35 and 37 of the specification as filed and in the claims as originally filed. Claim 80 is new. Support for claim 80 can be found throughout the specification, for example at paragraphs 1, 28, 32, 35 and 37 of the specification as filed and in the claims as originally filed. Claims 21, 23 and 24 are cancelled. Claims 1-20, 28, 30-34, 39-40, 43-45 and 69-77 were cancelled previously. Claims 22, 25-27, 29, 42, 46-49, 51-54, 59-60, 62 and 64-68 are currently withdrawn from consideration.

This amendment also incorporates remarks made during the telephonic interview with the examiner on June 23, 2009.

Claim Rejection Based on Section 112, paragraph 2

In the Office Action at page 3, claims 21, 23-24, 35-38, 41, 50, 55-58, 61-63, 78 and 79 are rejected under Section 112, second paragraph. The Examiner claimed that the phrase "inducing

weight loss, attenuating, controlling and / or reducing weight gain" was repetitive because loss, attenuating, controlling and reducing are synonyms. Applicants respectfully traverse. However, solely to expedite prosecution, Applicant has amended the claims so that all allegedly repetitive terms have been eliminated.

Furthermore, the Office Action alleges that claims 21 and 23 were broader than the claim they depended upon. Applicant was cancelled these claims.

With these changes, the Applicant respectfully submits that the rejection under Section 112 are overcome and the application is now ready to issue.

Claims Rejections Based on Section 103(a)

Rejection Based on Norman in view of Xue

In the Office Action at page 7, claims 21, 23-24, 38, 41, 50, 55-58, and 61-63 are rejected under 35 USC 103(a) as unpatentable over U.S. Patent Number 6103709, to Norman, in view of Xue, *The Agouti Gene Products Inhibits Lipolysis in Human Adipocytes via a Ca²⁺-Dependent Mechanism*, FASEB J, vol. 12, p. 1391-1396, Oct 1998. The Applicant respectfully disagrees.

Norman is a patent directed at the use of 1α , 25-dihydroxyvitamin D_3 analogs to treat Vitamin D related diseases. 1α , 25-dihydroxyvitamin D_3 is used in a therapeutically effective amount to treat diseases caused by a deficiency or overproduction of Vitamin D metabolites, of which 1α , 25-dihydroxyvitamin D_3 is one. Norman teaches that 1β , 25-dihydroxyvitamin D_3 is a 1α , 25-dihydroxyvitamin D_3 antagonist. Norman also teaches that both 1α , 25-dihydroxyvitamin D_3 and 1β , 25-dihydroxyvitamin D_3 bond to the VDR_{mem} receptor. When a VDR_{mem} receptor is linked to a calcium channel, the channel will allow Ca^{2+} into the cell if 1α , 25-dihydroxyvitamin D_3 binds to the VDR_{mem} receptor.

The Norman patent describes the effect of 1α , 25-dihydroxyvitamin D_3 on two kinds of bone cells, osteoblasts and osteoclasts, and one kind of intestinal cell, intestinal epithelial cells. The effect of 1α , 25-dihydroxyvitamin D_3 on each of these cells is different. 1α , 25-dihydroxyvitamin D_3 is reported to cause osteoblasts to absorb Ca^{2+} . Column 12, lines 39-59. Norman found that 1α , 25-dihydroxyvitamin D_3 causes osteoclasts to release Ca^{2+} rather than absorb it. Column 19. Norman found that 1α , 25-dihydroxyvitamin D_3 causes osteoblasts to absorb Ca^{2+} to facilitate bone growth. On the other hand, Norman found that 1α , 25-dihydroxyvitamin D_3 causes osteoclasts

to release Ca^{2+} into the blood stream, logically reducing the intracellular concentration of Ca^{2+} in the osteoclast. Norman reports that $1\alpha, 25\text{-dihydroxyvitamin D}_3$ causes an increase in intracellular Ca^{2+} concentrations in intestinal epithelial cells as part of transcalcitachia. Columns 21 & 24. But, Norman also describes that $1\alpha, 25\text{-dihydroxyvitamin D}_3$ is also the signal to export the same Ca^{2+} from the intestinal epithelial cell into neighboring capillaries using vesicles. Norman calls this process transcalcitachia because it is the transit of Ca^{2+} from the lumen of the intestines, through the intestinal epithelial cells, into the blood within the capillaries. While $1\alpha, 25\text{-dihydroxyvitamin D}_3$ does cause a temporary increase in intracellular Ca^{2+} concentrations, $1\alpha, 25\text{-dihydroxyvitamin D}_3$ also causes a decrease in the Ca^{2+} concentration at the same time.

However, Norman does not disclose or suggest the claimed methods. For example, Norman does not disclose or suggest administering an antagonist of calcitrophic hormone ($1,25\text{-(OH)}_2\text{-D}$) activity selected from the group consisting of $1\text{-}\beta, 25\text{-dihydroxyvitamin D}$, a homolog of $1\text{-}\beta, 25\text{-dihydroxyvitamin D}$, an isomer of $1\text{-}\beta, 25\text{-dihydroxyvitamin D}$, and calcium, in an amount effective to block calcitrophic hormone ($1,25\text{-(OH)}_2\text{-D}$) activity in adipocytes of said individual, and said antagonist resulting

in said antagonist inducing weight loss, and/or increasing metabolic consumption of adipose tissue.

In the Office Action, the Examiner assumes that all cells utilize similar transport systems. The Examiner states "[i]t is taught that in cells that have a VDR_{mem} [receptor] linked to a calcium channel there is an increase in Ca^{2+} (calcium) ions moving into the cells which results in an increase in intracellular calcium concentrations. Opening of the calcium channel followed by the intracellular increase results in increased activities of the osteoblasts..." Office Action January 14, 2009, p. 8. Yet, as noted above, Norman also describes other transport systems where 1α , 25-dihydroxyvitamin D_3 results in the decrease of intracellular Ca^{2+} . While an increase can be found in osteoblasts, osteoclasts respond to 1α , 25-dihydroxyvitamin D_3 in the opposite manner, decreasing the concentration. Intestinal epithelial cells experience both increases and decreases in intracellular Ca^{2+} concentrations in response to 1α , 25-dihydroxyvitamin D_3 . In this case, 1α , 25-dihydroxyvitamin D_3 mediates the transport of Ca^{2+} ions through the intestinal epithelial cells, from the food in the lumen of the intestine to the plasma in the lumen of the capillary. These three examples demonstrate that a person skilled in the art could not assume that 1α , 25-dihydroxyvitamin D_3 would have any

particular effect on any given cell type, because its effects are unpredictable. These three examples demonstrate that the effect of $1\alpha, 25$ -dihydroxyvitamin D_3 , or any signaling chemical, is cell-specific and can not be generalized without experimental evidence to support the generalization. Furthermore, the literature on calcium and Vitamin D metabolism shows that the effect of both calcium and Vitamin D on body systems is unpredictable and can only be determined by experimentation. Attached are four articles regarding the effect of calcium and Vitamin D on diabetes, bone fractures, cancer, and body sway and hyperparathyroidism. Pittas, J Clin Endocrinol Metab, June 2007, 92(6) 2017-2029 (attached hereto as Appendix A); Porthouse, BMJ vol 330, April 2005 (Appendix B); Martinez, Cancer Epidemiology, vol 7 163-168, Feb 1998 (Appendix C); Pfeifer, JBMR, vol 15, num 6, June 2000 (Appendix D). These articles provide evidence of unpredictability in the art. In each of the above-listed papers, the researchers reported a unique effect of calcium and Vitamin D on metabolism and physiology. Clearly calcium metabolism is complex and unpredictable. Accordingly, Norman does not disclose or suggest the claimed methods, which recite administering an antagonist of calcitrophic hormone in an amount effective to block calcitrophic hormone ($1,25$ -(OH) $_2$ -D) activity

calcitrophic hormone (1,25-(OH)₂-D) activity in adipocytes, resulting in said antagonist inducing weight loss, and/or increasing metabolic consumption of adipose tissue.

The Examiner combines Norman with Xue to complete the 35 USC 103(a) rejection. Xue is an article that studies the effect of intracellular calcium on adipose cells. Xue concludes that an increase in intracellular calcium in adipose cells results in a decrease in lipolysis. Xue does study a number of adipose cell receptors, but does not mention VDR_{mem}, 1 α , 25-dihydroxyvitamin D₃, 1 β , 25-dihydroxyvitamin D₃, or any other Vitamin D metabolite.

Attached is a Declaration executed by inventor Michael B. Zemel. The Declaration states that the inventor did not expect Vitamin D metabolites to effect adipose cells. Clearly, just as the inventor (who is a person of at least ordinary skill in the art) did not know the effect that Vitamin D would have on adipose cell metabolism, so also a person of ordinary skill in the art would not have predicted such effects.

In addition the Declaration states that Dr. Zemel is also the author of the cited sections of the Xue article, and that a person of ordinary skill reading the sections of the Xue article authored by the inventor would not be able to predict the effect of Vitamin D on adipose cell metabolism. Thus a person skilled

in the art could not use Xue to determine if any of these chemicals have any effect at all on an adipose cell.

In view of the foregoing, applicants submit that the claimed methods are patentable over Norman and Xue, whether considered alone or in combination. A person skilled in the art would have no basis for predicting the effect of calcium on adipocytes based on the cited references. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejection Based on Norman in view of Xue and Jequier

In the Office Action at page 10, claims 35-37 are rejected under 35 USC 103(a) as allegedly being unpatentable over Norman in view of Xue, and in further view of Jequier. Am. J. Clin. Nutr. 1987. Applicant disagrees. Norman and Xue are discussed above. Jequier describes the Body Mass Indexes for Grade I, Grade II, and Grade III obesity. However, Jequier does not disclose or suggest anything regarding the effect of 1α , 25-dihydroxyvitamin D₃ on adipose cells. Thus Jequier does not cure the above-noted defects in Norman and Xue. Applicants respectfully request that this rejection be withdrawn.

Rejection Based on Science Daily in view of Summerbell

In the Office Action at page 12, claims 21, 23, 35-38, 50, 55-58, 61-63, and 79 are rejected under 35 USC 103(a) as allegedly being unpatentable over *Study: Calcium May Curb Weight Gain in Young Women*, <http://www.sciencedaily.com/releases/19991014199042107.htm>, April 21 1999 (hereinafter "Science Daily"), and Summerbell, et al, *Randomized Controlled Trial of Novel, Simple and Well Supervised Weight Reducing Diet in Outpatients*, *BMJ* 1998, 317: 1487-9. Applicant disagrees. The claimed methods possess novel features that the Science Daily article lacks and the Summerbell article does not supply. Furthermore, new claim 80 recites additional distinctions that further clarify the patentability of the claimed methods.

The pending claims recite a method of regulating body weight comprising administering to an individual regulating body weight an antagonist of calcitrophic hormone (1,25-(OH)₂-D) activity selected from the group consisting of 1-β, 25-dihydroxyvitamin D, a homolog of 1-β, 25-dihydroxyvitamin D, an isomer of 1-β, 25-dihydroxyvitamin D, and calcium, in an amount effective to block calcitrophic hormone (1,25-(OH)₂-D) activity in adipocytes of said individual, and said antagonist resulting in said antagonist inducing weight loss, and/or increasing metabolic consumption of adipose tissue.

The claimed methods are patentable over Science Daily. For example, Science Daily does not disclose or suggest administration to an individual regulating body weight an antagonist of calcitrophic hormone in an amount effective to block calcitrophic hormone activity in adipocytes of an individual. Accordingly, Science Daily does not disclose or suggest the claimed methods.

And in any event, a person of ordinary skill in the art upon reading Science Daily would not draw any conclusions from its purported teachings. A reference "must be evaluated for what [it] fairly teach[es] one of ordinary skill in the art." In re Inland Steel Co., 60 USPQ.2d 1396, 1401 (Fed. Cir. 2001) (internal citations omitted). A person of ordinary skill in the relevant art would not consider a sensational headline in a news article to constitute a "teaching" with any scientific validity. And a person of ordinary skill would not consider the purported "findings" to "fairly teach" anything of significance to a person of ordinary skill. Indeed, the lead researcher herself invites the reader to withhold judgment until "these findings are confirmed." In addition, several statements made in the article are of questionable scientific validity, such that a person of ordinary skill in the art would have waited until the data were published before deciding whether to lend any credence

to them. Accordingly, a person of ordinary skill would have given no weight to the purported "teachings" of Science Daily.

In Science Daily, the reported "findings" are acknowledged to be preliminary, and the lead researcher effectively cautions against drawing any conclusions from the preliminary findings until the findings are confirmed. In paragraph 14, Dr. Teegarden, the lead researcher on the study, notes that "if these findings are confirmed," then action based on the findings may be warranted. Thus, the lead researcher herself acknowledges that the reference, on its own, does not provide any basis for drawing any actionable conclusions related to calcium and weight loss. Accordingly, Science Daily does not "fairly teach" anything of value to a person of ordinary skill, but in fact invites the readers of the article to wait until the results are confirmed, presumably in a peer-reviewed, published article, before drawing any conclusions.

Also, several of the statements in Science Daily are of questionable scientific validity, and thus they would also prompt a person of ordinary skill in the art to withhold judgment on the findings until the data became available for evaluation. For example, Dr. Teegarden states that "for the women with calorie intakes of more than 1,900, we found that the calories take over, and any potential benefits of weight-control

from calcium are lost." A person of ordinary skill in the art would question this statement, as it is highly unlikely that any change in calcium's effect would occur at an absolute value for caloric intake, without regard for any of the many physiological factors (height, weight, metabolic rate, etc.) that could be expected to cause the effect to vary from person to person. Accordingly, a person of ordinary skill would conclude that Science Daily does not "fairly teach" anything related to the effect of calcium on weight loss, and would wait to review the published data before drawing any conclusions. Similarly, the statements that "women in the study who got their calcium from dairy sources . . . showed more benefits . . . than those who primarily used non-dairy sources" and that "it may suggest that there is something in milk that works to help regulate body weight" would cause a person of ordinary skill to wonder whether the researchers sufficiently controlled for effects based on other components in milk, and would thus withhold judgment until they were able to evaluate the published data.

For all of the above reasons, a person of ordinary skill at the time Science Daily was published would not have considered it to "fairly teach" anything of value regarding calcium and weight-related benefits, and would have withheld judgment until

they had an opportunity to evaluate the peer-reviewed, published data.

Evidence of what a person of ordinary skill would understand from Science Daily is provided in the corresponding peer-reviewed, published study in Lin et al., "Dairy Calcium is Related to Changes in Body Composition During a Two-year Exercise Intervention in Young Women", Journal of the American College of Nutrition, 2000, 19(6), 754-760 (hereinafter "Lin"). A later reference can be used as evidence of how a person of ordinary skill would have viewed an earlier reference, for example to determine whether a statement in an earlier document is inaccurate. See, e.g., In re Brana, 34 USPQ.2d 1436, 1441, 1442 n.19 (Fed. Cir. 1995) (using later-filed Declaration to verify the accuracy of a statement in the specification). The Lin reference is persuasive evidence that a person of skill in the art would conclude that Science Daily did not teach any meaningful connection between calcium and weight-related benefits. A person of ordinary skill in the art would have found that Science Daily reflects no scientific conclusions, just unfounded journalistic interpretations of incomplete and flawed data. Indeed, Lin's data flatly undermine the journalist's purported teachings recited in Science Daily. Furthermore, Lin establishes that Science Daily's purported

teachings are, at most, based on associative data without any mechanistic support, and a person of ordinary skill in the art would not infer causation from associative data without some mechanistic rationale to support such a conclusion. And some of the associations reported are so contrary to then-contemporary understanding in the art that the Lin authors themselves describe them as "perplexing." In short, the Lin study results demonstrate that a person of ordinary skill in the art would not have read Science Daily as teaching any relevant link, causative or otherwise, between dietary calcium and weight-related benefits sufficient to motivate a person of ordinary skill to administer calcium with a reasonable expectation that it would cause a metabolic change and lead to weight loss, as claimed. The references do not suggest a cause, a mechanism, or an effect within the scope of the pending claims.

For example, the Lin study actually failed to demonstrate that calcium, and not another component of milk, caused the observed weight benefits. Science Daily states that "women who got their calcium from dairy sources, such as milk, yogurt and cheese, showed more benefits of the weight control measures than did those who primarily used non-dairy sources... or calcium supplements." (Paragraph 12.) In fact, the Lin study found that non-dairy calcium had no effect on body weight, which

undermines the conclusion that calcium was the causative agent. See Lin et al., p. 758. Furthermore, because of shortcomings in their study design, the authors were unable to exclude the possibility that the observed weight changes were caused by an ingredient in milk other than calcium. In fact, the authors were forced to conclude that "another component of dairy products which was not analyzed in this study[,]" and not calcium, "could be the factor which influences body weight." *Id.* The authors also state that "[a]nother possibility is that, if total dietary calcium increases, another nutrient decreases," in which case the other nutrient, and not calcium, would be the causative agent. *Id.* These shortcomings may have resulted from the fact that the study was initially intended to evaluate the effects of calcium intake on bone density, not weight. Lin, p. 755. In short, the authors had no basis for the assertion in Science Daily that calcium may curb weight gain in young women.

Furthermore, the authors' attempt to elucidate a mechanistic rationale for their suggested association between calcium intake and weight changes further demonstrates the lack of support for their conclusions. In the Lin article, the authors discuss several calcium intervention studies that explore the role of calcium in adipocyte lipid metabolism to support their hypothesized mechanism for the calcium-weight

change association. However, the authors are forced to acknowledge that "[u]nfortunately, the published results of calcium intervention trials in this age group . . . cannot be compared to the results of the current study" because, among other reasons, "changes in weight and body fat may be specific to dairy products, not calcium supplementation alone[.]" Lin, p. 759. In the absence of a demonstration of causation, a person of ordinary skill in the art would not infer causation from associative data without some mechanistic rationale supporting such a conclusion. Accordingly, a person of ordinary skill in the art would not credit Lin's conclusions regarding calcium and weight-related benefits, and thus would lend no credence to similar statements in Science Daily.

The Lin article data also suggested several other associations that depart from prior research and conventional wisdom to such an extent that they call into question the validity of the study as a whole. For example, the study found a positive correlation between vitamin A intake and changes in body weight, which the authors characterize as "perplexing" and inconsistent with other research in the area. Lin, p. 759. In addition, the study also noted a correlation between increased cholesterol intake and weight loss. They offer no explanation for this extremely counterintuitive result, other than to note

that the result is "perplexing" and that "further investigation is warranted."

In summary, a careful analysis of the published study based on the same data that formed the basis for the Science Daily article compels the following conclusions: 1) the authors focus on an alleged association between increased calcium intake and weight changes, but the data supporting the association is speculative at best and some of the data actually refutes their conclusion; 2) the authors themselves acknowledge that they failed to exclude the possibility that a nutrient other than calcium was the causative agent, to the point that they acknowledge they do not have a basis for comparing their study to calcium intervention studies; 3) their data supported other, more "perplexing" associations between nutrients and weight loss that depart from previous research and conventional wisdom to such an extent that they call into question the validity of the study as a whole. Thus, Science Daily does not teach a person of ordinary skill that calcium may curb weight gain in young women. Accordingly, Science Daily does not disclose or suggest the claimed methods.

Indeed, far from being obvious over the study discussed in Science Daily, the discoveries that gave rise to the claims at issue constitute unexpected results. The scientific literature

is filled with associative data indicating that many nutrients are directly or inversely associated with obesity. As noted above, persons skilled in the relevant art (a) do not infer causality from associative studies, and (b) would always look for an alternative explanation unless a plausible mechanism were presented to accompany the associative study. Indeed, a person of skill in the art, after evaluating the conclusions in the Science Daily study as well as the asserted bases for those conclusions, would likely decide that the conclusions are off-base, and would instead pursue other possible explanations for the observed weight loss.

Summerbell does not cure the above-noted defects in Science Daily. For example, Summerbell does not disclose or suggest administration to an individual regulating body weight an antagonist of calcitrophic hormone in an amount effective to block calcitrophic hormone activity in adipocytes of an individual. Accordingly, Summerbell does not disclose or suggest the claimed methods.

The Examiner cites the Summerbell article as evidence that the use of calcium to cause weight loss in the obese is obvious. The Examiner notes the fact that the stated purpose of the Summerbell article is to test the hypothesis that lack of compliance is the source of most diet failures and that novelty

encourages compliance. Summerbell found a group of subjects who had not used a milk only diet and divided them into 3 groups: one using a milk only diet, a second using a diet of a milk plus one other food, and a third using a control diet consisting of a conventional balanced diet. Summerbell found that the milk only group lost the most weight. Summerbell concluded that this was due to greater compliance with the diet. Summerbell also noted that the milk only diet provided an energy deficit of 7 MJ (or 1671 kcal) per day, as opposed to the milk plus diet, which provided a deficit of 4 MJ (or 955 kcal) per day. Clearly, if both groups comply equally, the milk only group should lose more weight because they have the greatest deficit. By comparison, the Science Daily article, and the Lin article it reports, required no energy deficit for either the variable or the control groups. Thus based upon the Summerbell article, one could not determine if the weight loss is due to milk, compliance, or energy deficit. This is clearly a reason for a person skilled in the art to question the meaning of Summerbell, and thus teaches away from the conclusion that Summerbell supports the use of calcium to lose weight.

Summerbell concluded that the cause of the weight loss was greater compliance. Summerbell then stated "[w]e are not advocating milk only as a general long term reducing diet for

obese outpatients...." By comparison, the Science Daily article reports study results obtained over a two-year period. These statements would compel a person skilled in the art to conclude that the purported teachings of the Science Daily article and the Summerbell article are in conflict, and thus a person of ordinary skill in the art would not combine the references. And in any event, a person of ordinary skill in the art would discount the purported teachings of Science Daily regarding calcium and weight-related benefits for the reasons presented above, and thus would see no reason to combine Summerbell and Science Daily. Accordingly, for this reason as well, a person of ordinary skill would not combine the references to arrive at the claimed methods.

Furthermore, Summerbell does not even mention the term "calcium," or any other calcitrophic hormone antagonist recited in the claims. Summerbell choose the milk only diet because none of the subjects had previously tried a milk only diet. Milk is a complex substance that contains carbohydrates, fats and protein, as well as calcium and other chemicals. Summerbell does not select a portion of milk to highlight, except the energy deficit caused by the milk only diet. A person skilled in the art would understand that milk is this complex substance, and would not assume that calcium, rather than calorie content, is the weight

loss agent of milk. Thus Summerbell again teaches away from the claimed methods.

In addition, persons skilled in the art would have interpreted the Summerbell article as an article about behavior. An article by Heymsfield suggests that Summerbell is viewed as a behavior article. *Weight Management Using Meal Replacement Strategy: Meta and Pooling Analysis from Six Studies*, International Journal of Obesity (2003), 27, 537-549, Table 7 (attached hereto as Appendix E). Summerbell is considered a meal-replacement diet by Heymsfield (Heymsfield, p. 539 and Table 7 - Summerbell among 30 papers that met criteria for meal replacement studies), and Heymsfield states that meal replacement diets, like all low-calorie diets, involve "behavior modification." Heymsfield, p. 538. Thus, the Summerbell article was understood by persons skilled in the art as a study about behavior, rather than about food chemistry. Any suggestion that a person skilled in the art would interpret the Summerbell study as a study of food chemistry is engaging in impermissible hindsight reasoning. The reading of Summerbell presented in the Office Action is only possible in light of the work of the present inventor Zemel. Thus the claimed methods are not disclosed or suggested by the cited Summerbell reference, even in combination with the Science Daily reference.

Furthermore, the claimed methods also arise out of unexpected result of Zemel's research. Norman provides indications that 1α , 25-dihydroxyvitamin D₃ might increase intracellular concentrations of calcium ions, but also provides indications that 1α , 25-dihydroxyvitamin D₃ might decrease intracellular calcium ion concentration. Xue does not present any information at all on the question of the effect of 1α , 25-dihydroxyvitamin D₃ on adipose cells. No person skilled in the art could predict the outcome of the Zemel research. Thus it is incorrect to reject this application based upon 35 USC 103(a) because the results of the Zemel research, and the claimed methods, are so unexpected.

New claim 80 provides additional distinctions. Claim 80 recites administering to an individual regulating body weight two antagonists of calcitrophic hormone ($1,25-(OH)_2-D$) activity selected from the group consisting of $1-\beta$, 25-dihydroxyvitamin D, a homolog of $1-\beta$, 25-dihydroxyvitamin D, an isomer of $1-\beta$, 25-dihydroxyvitamin D, and calcium, in an amount effective to block calcitrophic hormone ($1,25-(OH)_2-D$) activity in adipocytes of said individual, and said antagonist resulting in said antagonist inducing weight loss, and/or increasing metabolic consumption of adipose tissue. The cited references do not

disclose or suggest, for example, the administration of two of the listed calcitrophic hormone antagonists.

In view of the foregoing, the claims are patentable over Science Daily and Summerbell, whether considered alone or in combination. Applicant respectfully requests that this rejection be withdrawn.

Rejection Based on Science Daily in view of Summerbell, Jequier and Peterson

In the Office Action at page 15, claim 78 is rejected under 35 USC 103(a) as being unpatentable over Science Daily in view of Summerbell and Jequier, and in further view of Peterson, Journal of Nutrition, 1992. Peterson states a number of non-dairy sources of calcium. Peterson does not add any new information that would lead a person skilled in the art to believe that calcium or the other recited calcitrophic hormone antagonists will cause weight loss, increase metabolism, or affect adipose tissue. Accordingly, Applicant submits that claim 78 is patentable over the cited references, whether considered alone or in combination. Applicant respectfully requests that this rejection be withdrawn.

The Applicant respectfully requests, if the claims are again rejected upon any combination of references, that the Examiner include an explanation, in accordance with M.P.E.P. § 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (POBA 1985) and Ex parte Levensgood, 28 U.S.P.Q.2d 1300 (PTOBA&I 1993). a "factual basis to support his conclusion that it would have been obvious" to make the combination.

Double Patenting

In the Office Action at page 17, claims 21, 23, 35-38, 50, 55-58, 61-63. and 78-79 are rejected on the grounds of non-statutory obviousness-type double patenting over claims 1-9 of U.S. Patent Number 6384087, also by the inventor. The Applicant has included a terminal disclaimer that will obviate the Double Patenting rejection.

In the Office Action at page 18, claims 21, 23, 35-38, 50, 55-58, 61-63. and 78-79 are rejected on the grounds of non-statutory obviousness-type double patenting over claims 1-7, and 10-15 of copending U.S. Appl. No. 10/827296. The copending application has been abandoned and that will obviate the Double Patenting rejection.

In the Office Action at page 20, claims 21, 23, 35-38, 50, 55-58, 61-63. and 78-79 are rejected on the grounds of non-statutory obviousness-type double patenting over claims 1-7, 10-

17, and 19-22 of copending U.S. Appl. No. 10/827307. The copending application has been abandoned and that will obviate the Double Patenting rejection.

In the Office Action at page 21, claims 21, 23, 35-38, 50, 55-58, 61-63. and 78-79 are rejected on the grounds of non-statutory obviousness-type double patenting over claims 1, 5-6, 28-37, 41-44, 46-53, 55, 57, 59-62, and 64-72 of copending U.S. Appl. No. 10/066057. The Applicant has included a terminal disclaimer that will obviate the Double Patenting rejection.

Conclusion

For at least the above reasons, the Applicant submits that the specification and claims are now in proper form, and that the claims are patentable over the prior art. Therefore Applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

The Applicant has amended the claims of this application so that they are proper, definite and define novel and nonobvious structure. If, for any reason this application is not believed

to be in full condition for allowance, the Applicant respectfully request the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P § 2173.02 and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

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Respectfully submitted,

Electronic signature: /Thomas F. Barry

Michael A. Gollin

Registration No.: 31,957

Thomas F. Barry

Registration No.: 57,586

VENABLE LLP

P.O. Box 34385

Washington, DC 20043-9998

(202) 344-4000

(202) 344-8300 (Fax)

Attorney/Agent For Applicant